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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,307	04/06/2001	David Mack	A-69192-1/DJB/JJD/AMS	7761

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EXAMINER
KIM, YOUNG J

ART UNIT	PAPER NUMBER
1637	9

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/828,307	MACK ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 4/06/01 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary Remark

Applicants are advised that the application contained two claims which were numbered as claim 44. The second occurrence of claim 44 has been renumbered to claim 45 and the subsequent claim has been renumbered to claim 46 (37 CFR 1.126)

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a method of screening for drug candidates via protein expression profile (CZA8), wherein said protein has a sequence of SEQ ID NO: 2 or SEQ ID NO:4 (splice variant), classified in class 436, subclass 500.

II. Claim 5, drawn to a method of screening for a bioactive agent capable of binding to CZA8 (SEQ ID NO: 2 or SEQ ID NO: 4), classified in class 530, subclass 387.1.

III. Claims 6-8, 12-19, 22, and 23, drawn to a method of screening for modulators of CZA8, an antibody which modulates (inhibits) the activity of CZA8, classified in class 424, subclass 130.1.

IV. Claim 11, drawn to a method of diagnosing cancer via expression profile comparison, classified in class 435, subclass 6.

V. Claims 20 and 21, drawn to a method of screening for a bioactive agent which interferes with the binding of CZA8 and its antibody, classified in class 424, subclass 184.1.

VI. Claim 24, drawn to a method for neutralizing the effect of CZA8 with an agent, classified in class 514, subclass 1.

VII. Claims 25 and 26, drawn to a method of treating breast cancer with an inhibitor to CZA8, wherein said inhibitor is an antibody, classified in class 424, subclass 130.1.

VIII. Claims 27-32, drawn to a method of localizing a therapeutic moiety to breast and/or colorectal cancer via antibody conjugated to said therapeutic moiety, classified in class 424, subclass 178.1.

IX. Claims 33 and 34, drawn to a method for inhibiting breast and/or colorectal cancer via antisense, classified in class 514, subclass 44.

X. Claim 35, drawn to a biochip comprising fewer than 1000 probes, classified in class 536, subclass 23.1.

XI. Claims 36 and 37, drawn to a method of eliciting immune response, classified in class 436, subclass 501.

XII. Claims 9, 10, and 38, drawn to a method for determining prognosis of an individual with breast and/or colorectal cancer via protein expression monitoring, classified in class 530, subclass 300.

XIII. Claims 39-44, drawn to an isolated polypeptide of SEQ ID NO: 2 or its splice variant (SEQ ID NO: 4), classified in class 530, subclass 300.

XIV. Claims 45 and 46, drawn to an isolated nucleic acid of SEQ ID NO: 1 or its splice variant (SEQ ID NO: 3), classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX, XI, and XII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions employ different sub-steps, different compositions/products, to achieve different outcomes. For example, Inventions IV, IX, XI are unrelated to Inventions I-III, V-VIII, and XII because Inventions IV, IX, XI require nucleic acids while Inventions I-III, V-VIII, and XII requires a protein, thus not capable of being used together, requiring products that differ in functions to become drawn to different outcomes. Although Inventions IV, IX, and XI require nucleic acids in their methods, they are drawn to materially different process: Invention IV is drawn to an expression assay while Invention IX is drawn to an antisense therapy, while Invention XI is drawn to eliciting immune response. Inventions I-III, V-VIII, and XII are also different for similar reasons. For example, Invention I is drawn to method of screening for drug candidates (requiring drugs) by looking at the expression of protein CZA8, while Invention II is drawn solely to a method of screening for a bioactive agent which binds the protein CZA8 (not requiring any drug candidates nor modulating the activity), while Invention III is drawn to a modulator which influences the activity of CZA8. Invention V is drawn to a method of screening for a bioactive agent which interferes with the binding of CZA8 and its antibody, requiring a materially different compound, while Invention VI is drawn to a method of neutralizing (or modulating in broad sense) the activity of CZA8 but via different compound, a product that is materially different. The method of Invention VII requires an antibody that is to inhibit the activity of CZA8, thus similar to Invention III. However, Invention VII is determined to be materially different, posing a search burden, because the method of Invention VII

"requires" that such inhibition "treat" breast cancer. Such limitation would require a search that would not be coextensive to a method just screening for modulators that would modulate the activity of CZA8. The method of Invention VIII is also determined to be materially different because it requires a therapeutic moiety that is not required in any of the above methods. Finally, Invention XII is determined to be materially different because the method is drawn to a prognosis of a patient via expression profiling. Although Invention IV also uses the art of expression profiling, its method is drawn to a method of diagnosing cancer, thus using profiling as a tool for diagnosis, while the method of Invention IV employs the expression profiling for prognosis of a therapy, a materially different process.

Inventions X, XIII, and XIV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different physical structures and functions.

Invention X is unrelated to Inventions I-III, V-IX, and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions I-III, V-IX, and XI do not require the biochip of X.

Inventions X is related to Inventions IV and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the biochip of Invention X could be used in either of the materially different methods of IV and XII.

Invention XIII is related to Inventions I-III and V-VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of XIII could be used in any one of the materially different methods of I-III and V-VIII.

Invention XIII is unrelated to Inventions IV, IX, XI, and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions IV, IX, XI, and XII do not require the polypeptide of XIII.

Invention XIV is unrelated to Inventions I-III and V-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions I-III and V-VIII do not require the polynucleotide of XIV.

Inventions XIV is related to Inventions IV, IX, XI, and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the polynucleotide of Invention XIV could be used in any one of the materially different methods of IV, IX, XI, and XII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was not made to request an oral election to the above restriction requirement due to the complex nature of the requirement (MPEP § 812.01).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

9/10/02

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
9/16/02